

claims. Similarly claims 10 and 17 have been amended to recite a microorganism in the preamble and the body of the claim.

**§102 Rejection**

In the Official Action, claims 1-27 were rejected as anticipated by Smith 5,614,412. However, Smith does not disclose features in independent claims 1, 10 and 17. Accordingly, Applicant requests that the Examiner reconsider the rejection of the claims.

Smith is directed to a carrier 10 for carrying several flexible containers 15. The device includes a pump 40 that is operable to fill the containers 15 with a mixture of cells and a fluid. The containers 15 have an access port 45 at the top so that the fluid can be filled into the containers from the top. See col. 5, lines 46-51.

The pump 40 pumps a mixture of cells and fluid into the containers 15 based on parameters input into the pump controls 42. More specifically, an operator inputs the volume to be delivered on the pump control module 42. Col. 6 lines 22-23. The specific gravity of the supply fluid is also entered into the pump control module 42. Col. 6 lines 24-25. A clamp 60 that closes off the first container 15a is then opened so that fluid can flow into the first container 15a. The pump is started to deliver fluid into the first container. An alarm is sounded when the desired volume has been delivered to the first container 15a. Col. 6 lines 27-30. The clamp 60a to the first container 15a is then closed and the clamp to the second container is opened to fill the second container.

As described above, the pump 40 is used to fill the containers prior to culturing the cells rather than controlling the flow of fluid while the cells are being cultured. In addition, the pump is controlled based on criteria entered by the operator rather than on feedback from a detected characteristic.

In contrast to Smith, claim 1 recites the step of aerating a cell suspension. The Official Action makes a blanket statement that the claims are identical to the disclosure of Smith without providing any support for this statement. There is no mention of the step of aerating a cell suspension in Smith. There is no mention of detecting a characteristic of the cell suspension in Smith, and there is no mention of varying either the flow rate of the aerating fluid or the composition of the aerating fluid in response to the detected characteristic. As discussed above, Smith is simply directed to an improvement that allows multiple bags to be filled from a single setup with a single pump. The filling is based on parameters input from an operator and then shutting off the flow of fluid after an alarm goes off.

Applicant's claimed methodology recites varying either the flow rate of the aerating fluid (i.e. increasing or decreasing the flow of aerating fluid) or varying the composition of the aerating fluid (i.e. increasing or decreasing the amount of oxygen in the aerating fluid). There is no teaching or suggestion of such a step in Smith.

In light of the differences between claim 1 and Smith, claim 1 is patentably distinct from Smith. Accordingly, Applicant requests that the Examiner reconsider the rejection of claim 1 and dependent claims 2-9.

Referring to claim 10, the claim recites the step of attaching a liner to a closure to close the opening in the liner. As shown in the Figures, and described in the specification, Applicant's methodology includes the steps of attaching a disposable liner 30 to a closure, such as a head plate 40. In the example provided in the specification, the liner is similar to a plastic bag. The closure closes the opening of the liner to create a reservoir.

In contrast, Smith uses preformed sealed containers that have an access port 45. Therefore, Smith does not teach or suggest the step of attaching a liner to a closure to close an opening in the liner as recited in claim 10. Accordingly,

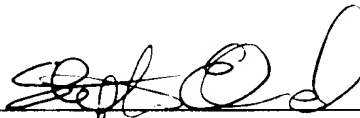
claim 10, and dependent claims 11-16, are patentably distinct from Smith. Similarly, claim 17 recites the steps of providing a plastic reservoir having an opening and closing the opening. Since Smith does not teach or suggest such steps, claim 17, and dependent claims 18-27, are patentably distinct from Smith.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

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By



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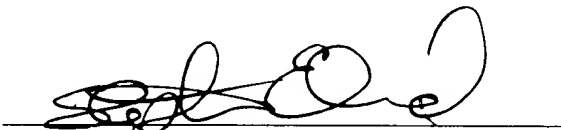
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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this Response and accompanying papers are being deposited on **May 14, 2002** with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231

May 14, 2002

Date of Certificate



Stephen H. Eland

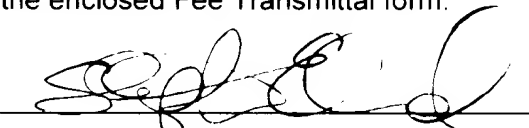
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**Petition for Extension Under 37 CFR §1.136(a)**

Applicant's undersigned attorney hereby petitions for an extension of time of 2 month(s) beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

May 14, 2002

Date of Certificate



Stephen H. Eland

PTO Registration No. 41,010

**ATTACHMENT A**

1. (Amended) A method for culturing cells or microorganisms, comprising the steps of:
  - providing a flexible sterile plastic reservoir;
  - introducing a culture media into the reservoir;
  - inoculating the culture media with a cell or microorganism to provide a cell suspension;
  - aerating the cell suspension[s] with a fluid at a flow rate;
  - detecting a characteristic of the cell suspension; and
  - varying at least one of the flow rate of the aerating fluid and the composition of the aerating fluid in response to the detected characteristic.
3. (Amended) The method of claim 1 comprising the step of circulating the cell suspension[s].
6. (Amended) The method of claim 4 wherein the step of aerating comprises aerating the cell suspension[s] through the port in the closure.
10. (Amended) A method for culturing cells and/or a microorganism[s], comprising the steps of:
  - providing a disposable liner forming a reservoir having an opening;
  - attaching the liner to a closure to close the opening;
  - introducing into the reservoir a cell suspension comprised of culture medium and one of cells or a microorganism;
  - culturing the cells or microorganism in the reservoir;
  - detaching the liner from the closure after culturing the cells or microorganism;
  - and
  - attaching a second liner to the closure.

17. (Amended) A method for culturing cells and/or a microorganism[s], comprising the steps of:
- providing a first flexible plastic reservoir having a first opening;
  - introducing a culture media into the first reservoir;
  - introducing cells or a microorganism into the first reservoir;
  - closing the first opening;
  - providing a second reservoir having culture media;
  - circulating the culture media between the first reservoir and the second reservoir through the first opening.